



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1564]

Ferndale Laboratories, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of nine abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040259	Hydrocortisone Acetate Cream USP, 2.5%	Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220
ANDA 040457	Pyridostigmine Bromide Tablets USP, 60 milligrams (mg)	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544
ANDA 061806	Cloxacen (cloxacillin sodium) Capsules, Equivalent to (EQ) 250 mg base and EQ 500 mg base	GlaxoSmithKline, LLC, 5 Crescent Dr., Philadelphia, PA 19112
ANDA 065453	Vancomycin Hydrochloride (HCl) Capsules USP, EQ 125 mg base and EQ 250 mg base	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 075836	Calcitriol Injection, 1 microgram (mcg)/milliliter (mL) and 2 mcg/mL	Do.
ANDA 075916	Rimantadine HCl Tablets USP, 100 mg	Impax Laboratories, Inc.
ANDA 076731	Glyburide and Metformin HCl Tablets USP, 1.25 mg/250 mg, 2.5 mg/500 mg, and 5 mg/500 mg	Do.
ANDA 076889	Fluconazole in Sodium Chloride 0.9% Injection, 200 mg/100 mL and 400 mg/200 mL	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 088572	Pediatric LTA Kit (lidocaine HCl) Solution, 2%	Abbott Laboratories, One Abbott Park Rd., Abbott Park, IL 60064

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

